BIOTECHNOLOGY EQUITY RESEARCH

Tiziana Life Sciences (TLSA, Buy, $7 PT)

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Phase 2a INFORM-MS Trial Readout Shows Reduction in Brain Inflammation and, Potentially Closing the Loop to Clinical Efficacy, Improvements in Fatigue.

WHAT YOU SHOULD KNOW: The role of inflammation in neurodegeneration is broadly accepted and, as we reviewed HERE, it may be essential to clam rogue immune cells before other more target-specific corrective approaches can restore function. We see Tregs as one of the heaviest buttons that can be pushed to normalize immune function and the earlier data from foralumab made it clear the approach was very effective at reducing inflammation in the regions that need it. These promising results still left open the question of: would reducing inflammation in a brain that was significantly over-inflamed result in meaningful clinical benefit? This: "can the damage be reversed or slowed" question has been the bane of neurological research as several established disease risk factors have been corrected only to reveal that it's too late to back up the damage. Today's TLSA readout looks to be a significant step in showing that inflammation may be an attractive approach to monotherapy and more likely an important partner for combination with more specific correction approaches. **Today's details.** The INFORM-MS Phase 2a topline data came in better than expected — the trial not only delivered a statistically significant reduction in microglial activation on TSPO PET, but also **produced a statistically significant improvement in fatigue on MFIS**, a result we did not anticipate as the base case given the short 12-week treatment window. The bar we set heading into this readout was ~75% of patients showing a TSPO signal reduction as a positive result. The trial cleared that bar and then some, adding a clinical endpoint win that meaningfully de-risks the path forward. The 48-patient, randomized, double-blind, placebo-controlled trial met both dual primary endpoints. On the imaging primary, the 50 µg arm achieved a statistically significant reduction in white matter SUVR versus placebo (adjusted treatment difference of -0.0231, p=0.0168) in the ANCOVA of 40 analyzable PET patients — a result that mirrors the reductions previously published in the expanded access program, now replicated in a controlled setting. The 100 µg arm did not reach statistical significance on PET, likely a function of the small sample size in that arm (n=11).

- **Does this energize the field?** The fatigue result is the headline surprise. The study was not powered to demonstrate a statistically significant clinical effect — and yet it did. The MFIS Total Score declined by -6.17 points in the 50 µg arm (p=0.035) and -7.18 points in the 100 µg arm (p=0.040), versus only -3.12 in placebo — both exceeding the established 4-point threshold for clinical significance, and both reaching statistical significance versus their own baselines. The approximately twofold greater improvement in both foralumab arms relative to placebo further reinforces that this is a real signal, not noise. No change was seen in EDSS over the 3-month duration, which is unsurprising — EDSS is a notoriously insensitive measure over short intervals in a slowly progressing disease, and we would not read the flat EDSS as a negative. Next steps include full data analysis, presentation at an upcoming scientific congress, and an FDA engagement to discuss the development path forward in na-SPMS.
- **On safety**, both doses were clean: all 48 participants completed treatment, there were no deaths, no discontinuations due to adverse events, and no study drug-related SAEs — an important confirmation after 37 patient-years of exposure with no serious AEs reported to date. Treatment-emergent ...**Continued on P3**
- **Valuation:** We value TLSA using a DCF (17.0% discount rate and a 1.0% TG rate).

Company Data	
Closing Price	$0.90
Price Target	$7.00
Market Cap (M)	$115.69
Shares Out (M)	127.87
Avg Daily Vol-3 Months (M)	0.75

Revisions	Previous	Current
Rating	Buy	Buy
Price Target	$7.00	$7.00
FY26E EPS	(0.18)	(0.18)
FY27E EPS	(0.18)	(0.19)
FY26E NI	(21.66)	(23.62)
FY27E NI	(22.20)	(24.21)

EPS (GAAP)			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(0.05)	(0.10)**A**	(0.09)
Q3	-	-	-
Q4	(0.11)	(0.10)	(0.10)
FY EPS	**(0.16)**	**(0.18)**	**(0.19)**
FY P/E	-	-	-

Net Income			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(5.63)	(12.39)**A**	(11.66)
Q3	-	-	-
Q4	(12.80)	(12.24)	(12.55)
FY NI	**(18.43)**	**(23.62)**	**(24.21)**

Source: FactSet, BTIG Estimates and Company Documents reported as $ currency.
FY = Fiscal Year **CY** = Calendar Year

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Investment Thesis

The foralumab approach seems a straightforward approach to stimulating Treg production, and Tregs are an extremely well-validated modulator of the immune system. As a result, we see the Tiziana programs to be relatively de-risked and the degree and timeline for correction of patients' disease is the big readout. The company is continually generating additional clinical data with readouts in SPMS, MSA and AD all expected in the next 12 months. In each case we expect data sets that corroborate the biomarkers seen to date and continue to support the thesis that true clinical benefit will be seen in larger trials with longer treatment periods.

Upcoming Catalysts

- Multiple System Atrophy (MSA) Phase 2a updates - YE2026
- Early Alzheimer's Disease Phase 2 Initial efficacy or biomarker data - 1H27

Base Case Assumptions: **$7 Price Target**

Both the SPMS P2a readout and the ongoing cohorts of MSA patients continue to show reductions in CNS inflammation in foralumab-treated patients. Signs of clinical activity are reported from the early trials.

TZLS-401 for SPMS - 50% PoS. 2030 market entry. Peak penetration of 15%. Price of $70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for MSA - 30% PoS. 2031 market entry. Peak penetration of 25%. Price of $70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for AD - 15% PoS. 2032 market entry. Peak penetration of 5%. Price of $70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for ALS - 15% PoS. 2032 market entry. Peak penetration of 15%. Price of $70,000 per patient per year with prices increasing 1.5% annually.

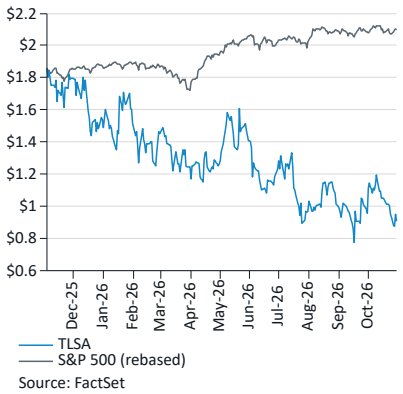
Upside Scenario

Strong signs of clinical activity that correlate with biomarker readouts like TSPO imaging are reported.

Downside Scenario

Biomarker readouts are less robust and only seen in a handful of patients. Any toxicity would be a negative surprise after the company has reported no serious AEs after 37-patient years of exposure to foralumab.

Price Performance



Source: FactSet

Company Description

Tiziana Life Sciences is a clinical-stage biotechnology company focused on developing therapies for neuroinflammatory and neurodegenerative diseases. The company's lead asset, foralumab — believed to be the only fully human anti-CD3 monoclonal antibody in clinical development — is being evaluated intranasally across multiple indications, including non-active secondary progressive multiple sclerosis (na-SPMS), Alzheimer's Disease, amyotrophic lateral sclerosis (ALS), and Multiple System Atrophy (MSA).

- ...adverse events were actually numerically lower in the foralumab arms (76.7% combined) than in placebo (83.3%), with the most common events being headache, fall, nasal congestion, and rhinorrhea.
- **Interim update.** TSLA has reported their 1H26 financial results in a recent interim update and the model has been updated accordingly.
- **ALS: looks essential to fix inflammation first.** ALS is possibly the most compelling test case for the role of inflammation in driving neurodegeneration and the disease is results in high levels of inflammatory markers, Nf-L elevations (damaged neurons) and documented impairment of Treg function. Similarly, QALSODY, a drug thought to fix the molecular defect in the subgroup of ALS patients with SOD1 mutations (likely causing both loss of function and gain of function toxicities) was approved based on clear benefits to Nf-L levels, but after about 3 years of treatment only about 25% of patients are showing clinical benefits. Although a benefit to patients, these results seem a long way from other corrections such as EDTs in Hunter syndrome (AVLAYAH) or ASO treatments in SMA (SPINRAZA) or Dravet (zorevunersen). Tiziana is exploring the idea that ongoing chronic inflammation may be the culprit in these very modest treatment effects in ALS relative to similarly horrific disease states. The foralumab ALS program is the earliest and most exploratory of Tiziana's four programs, but we see the approach as one of the most scientifically important. On September 28th, Tiziana announced that the first three participants have been dosed, marking the formal opening of the trial. The BANYAN trial is a 44-patient, 3:1 randomized, placebo-controlled study enrolling early ALS patients (≤24 months since symptom onset) across four sites: the Healey & AMG Center in Boston, the Les Turner ALS Center at Northwestern Medicine in Chicago, University of Minnesota in Minneapolis, and Nova Southeastern University in Davie, FL. Management expects full enrollment within ~6 months, with data readouts at both three and six months — putting a substantive data read near the end of 2Q27. The trial will enroll all ALS subtypes, reflecting **management's view that neuroinflammation is a universal feature of the disease regardless of genetic or clinical subtype**. The primary endpoint is safety, with key secondary and exploratory endpoints centered on biomarkers: Treg and T-cell subset profiling, single-cell RNA sequencing of T-cell subpopulations, changes in neurofilament light chain (NfL), and microglial activation via TSPO-PET/MRI. Of these, NfL is the signal management is most focused on — a reduction here would be an FDA-accepted early indicator of biological activity.
- **AD: all the wrong cells in all the right places.** Tiziana's AD program adds a particularly interesting dimension to the foralumab story by addressing a gap that even approved therapies have failed to close. TSPO-PET imaging has confirmed that anti-amyloid therapies like lecanemab reduce plaque burden but leave microglial activation unresolved where neuroinflammation persists as an independent pathological driver. This incomplete effect on disease progression may reflect the mechanistic feature of the two approved Ab-mAbs bind inert plaque and can only fully neutralize the toxic Ab oligomers once plaque has cleared. Approaches to remove specifically the toxic oligomers as seen with Acumen (ABOS, Buy, $1 TP) may be better than the anti-amyloids in reducing inflammation, and **landmark data are expected around year-end**. Based on direct imaging data, Foralumab also looks poised to address this gap. The Phase 2 trial, which dosed its first patient in December 2025 and has now enrolled 15 patients, evaluates intranasal foralumab over a 3-month treatment period in patients with early AD — with eligibility open to patients both on and off anti-amyloid therapy. Primary endpoints are anchored in TSPO-PET imaging alongside cognitive assessments and biomarkers including amyloid, tau, NfL, and GFAP, with data expected in early 2027. The most meaningful signal to watch for will be a reduction in neuroinflammation across both patient populations — those on anti-amyloids and those off — which would powerfully reinforce the core thesis that microglial activation is an independent, persistent driver of disease that requires direct targeting, regardless of amyloid burden. A positive read in the anti-amyloid-treated cohort in particular would be a clinically differentiated result, given the well-documented finding that plaque clearance leaves neuroinflammation intact.
- **MSA: small population with big inflammation.** Alteration aside, MSA represents arguably the most compelling unmet need in the Tiziana pipeline — a rapidly progressive, universally fatal neurodegenerative disorder with no approved disease-modifying therapies and a median survival of 6–9 years from diagnosis. On September 30th, Tiziana filed for Orphan Drug Designation with the FDA for intranasal foralumab in MSA. The ongoing Phase 2a trial is structured more as a compassionate use/case series than a traditional controlled trial, but the emerging data have been encouraging. Of the four patients dosed to date two have reported anecdotal functional improvement, and a third patient showed a reduction in brain inflammation on PET as of the most recent July 2026 update. Management plans to dose an additional five patients, specifically targeting those earlier in the disease course where treatment effect may be more detectable. A trial update is expected later during November. Looking further ahead, management is exploring an accelerated approval pathway that would allow a pivotal trial built on surrogate endpoints — envisioning a ~40-patient study, potentially running in 2028 with an approval submission by year-end 2028.

INCOME STATEMENT

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Tiziana Life Sciences (TLSA) Income Statement

Period Ending $USD ('000s)	Dec-21 2021A	Dec-22 2022A	Dec-23 2023A	Dec-24 2024A	Jun-25 1H25A	Dec-25 2H25A	Dec-25 2025A	Jun-26 1H26A	Dec-26 2H26E	Dec-26 2026E	Dec-27 2027E
Product Revenue:											
TZLS-401 for SPMS (50% risk adjusted)							-	-	-	-	-
TZLS-401 for MSA (30% risk adjusted)							-	-	-	-	-
TZLS-401 for AD (15% risk adjusted)							-	-	-	-	-
TZLS-401 for ALS (15% risk adjusted)								-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	-	-	-
Operating Expenses:											
Cost of goods sold	-	-	-	-		-	-	-	-	-	-
Research and development	13,208	12,955	8,113	5,229	3,243	7,036	10,279	6,431	7,212	13,643	13,984
General and administrative	13,311	1,631	9,871	10,565	5,943	4,910	10,853	4,943	5,033	9,976	10,225
Other	855										
Total Operating Expenses	**27,374**	**14,586**	**17,984**	**15,794**	**9,186**	**11,946**	**21,132**	**11,374**	**12,245**	**23,619**	**24,209**
Operating Income (Loss) EBIT	**(27,374)**	**(14,586)**	**(17,984)**	**(15,794)**	**(9,186)**	**(11,946)**	**(21,132)**	**(11,374)**	**(12,245)**	**(23,619)**	**(24,209)**
Other Income (expense) Net	717	(811)	742	(952)	3,554	(853)	2,701	(1,013)			
Income (Loss) before Taxes	**(26,657)**	**(15,397)**	**(17,242)**	**(16,746)**	**(5,632)**	**(12,799)**	**(18,431)**	**(12,387)**	**(12,245)**	**(23,619)**	**(24,209)**
Tax provision	3,240	-	**(449)**	4,883	0	0	0	0			
Net Income (Loss)	**(23,417)**	**(15,397)**	**(17,691)**	**(11,863)**	**(5,632)**	**(12,799)**	**(18,431)**	**(12,387)**	**(12,245)**	**(23,619)**	**(24,209)**
Foreign currency translation adjustment	(4,478)	(3,582)	1,492	(72)	339	(427)	(88)	22			
Total comprehensive income (Loss)	**(27,895)**	**(18,979)**	**(16,199)**	**(11,935)**	**(5,293)**	**(13,226)**	**(18,519)**	**(12,365)**	**(12,245)**	**(23,619)**	**(24,209)**
Basic EPS, GAAP	**(0.24)**	**(0.15)**	**(0.17)**	**(0.11)**	**(0.05)**	**(0.11)**	**(0.16)**	**(0.10)**	**(0.10)**	**(0.18)**	**(0.19)**
Diluted EPS, GAAP	**(0.24)**	**(0.15)**	**(0.17)**	**(0.11)**	**(0.05)**	**(0.11)**	**(0.16)**	**(0.10)**	**(0.10)**	**(0.18)**	**(0.19)**
Weighted average shares outstanding, basic	97,932	101,526	102,471	106,672	116,827	119,739	118,283	127,874	128,124	127,999	128,874
Weighted average shares outstanding, diluted	97,932	101,526	102,471	106,672	116,827	119,739	118,283	127,874	128,124	127,999	128,874

Source: BTIG Research estimates

BTIG Covered Companies Mentioned in this Report

Tiziana Life Sciences (TLSA, Buy, $7 PT; Closing Price: $0.90)
Acumen Pharmaceuticals (ABOS, Buy, $1 PT; Closing Price: $2.29)

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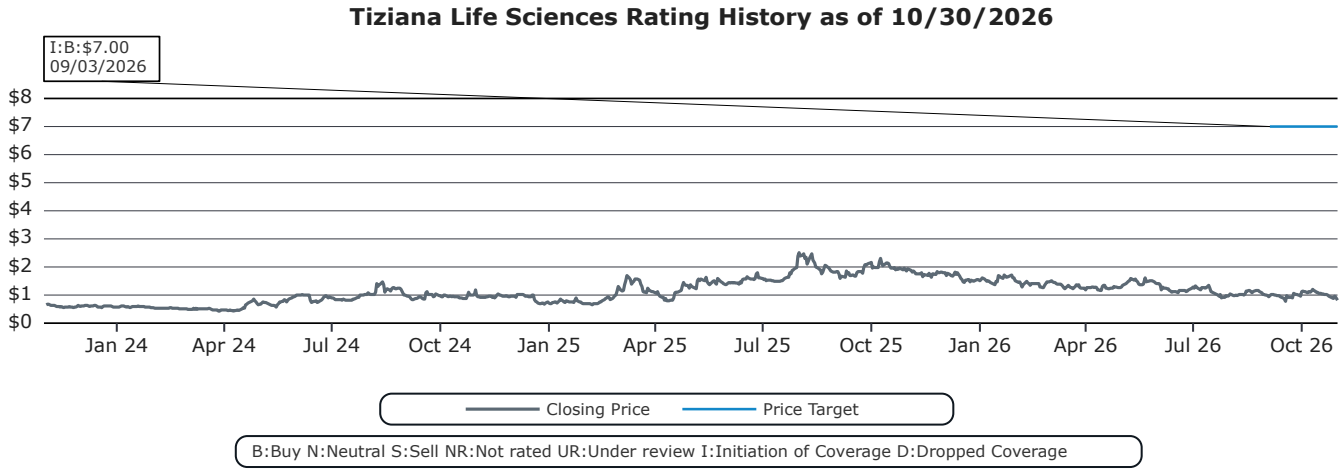
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Neutral	172	31.2%	Neutral	48	27.9%
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Tiziana Life Sciences (TLSA, Buy, $7 PT)

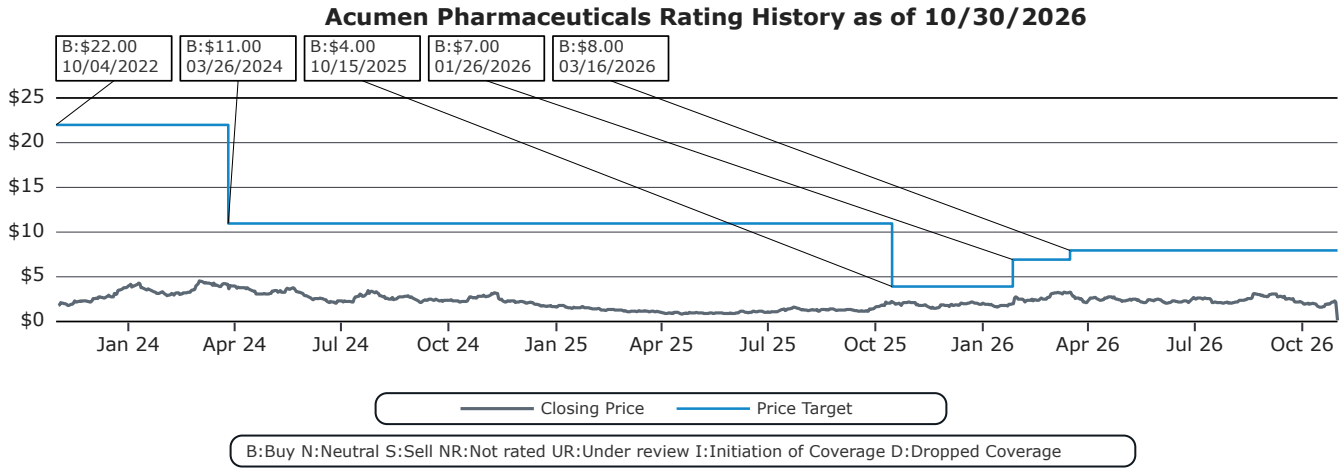
Valuation: We value TLSA using a DCF (17.0% discount rate and a 1.0% TG rate)
Risks: Tiziana is an established biotech company. It faces all the standard upside and downside risks for that industry, including unexpected outcomes or safety signals from clinical readouts, regulatory uncertainty, and increasingly complex and price-sensitive commercial markets for its product candidates.



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